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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,615	02/08/2001	Kaname Nakahara	216208US0XPCT	8496

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/16/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,615

Applicant(s)

NAKAHARA ET AL.

Examiner

Humera N Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2002 (paper no. 10).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,10-18 and 21-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-9, 19, 20 and 32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the Election of Species filed 07/03/02.

Claims 1, 4-9, 19, 20 and 32-36 are pending. Claims 1, 4-9, 19, 20 and 32-36 are rejected.

The applicant's generic claims have been rejected. Claims 2, 3, 10-18 and 21-31 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 19, 20 and 32-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Pfister *et al.* (US Pat. No.5, 232,702), (collectively, "Pfister").

Pfister et al. teach a silicone pressure-sensitive adhesive transdermal drug delivery patch comprising five layers of a support body, medicament, rate controlling membrane, adhesive and a release liner with the inclusion of cardiovascular agents, anti-anginal agents and polyvinyl alcohol (see reference column 2, lines 5-45); (column 5, lines 25-40); (column 8, lines 28-68); (column 9, lines 1-23).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4-8, 19, 20 and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfister *et al.* (US Pat. No.5, 232,702).

Pfister et al. teach a silicone pressure-sensitive adhesive transdermal drug delivery patch, as described above, comprising five layers of a support body, medicament, rate controlling membrane, adhesive and a release liner with the inclusion of cardiovascular agents, anti-anginal agents and polyvinyl alcohol (see reference column 2, lines 5-45); (column 5, lines 25-40); (column 8, lines 28-68); (column 9, lines 1-23). Pfister et al. does not explicitly teach the properties of water-vapor permeability of 100-g/m square or more at 40c and 24 hours for the adhesive. However, it would have been deemed obvious to one of ordinary skill in the art at the time the invention was made that suitable vapor permeability ranges could be determined through routine or manipulative experimentation and in addition, since the materials used by Pfister et al. are the same, they would also provide for similar properties and results as the claimed invention.

Pfister, while teaching a transdermal drug-delivery patch comprising various drugs, such as, cardiovascular agents and anti-anginal agents, do not explicitly teach nicorandil in the formulation.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (US Pat. No. 5, 446,070).

Mantelle teaches compositions and methods for topical administration of pharmaceutically active agents, wherein the composition is in the form of a bioadhesive suitable for a variety of drugs, such as anti-anginal agents and vasodilators, such as nicorandil (see reference column 4, lines 25-44); (col. 12, lines 10-15); (col. 41, lines 9-20). Therefore it would have been obvious to one of

ordinary skill in the art at the time the invention was made to use the bioadhesive composition of Mantelle, who teaches the incorporation of nicorandil in a bioadhesive formulation, with the expected result of obtaining an improved nicorandil preparation.

Note: Examiner points out that claim(s) containing both nicorandil and polyvinyl alcohol would be allowable.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600